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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/198,004	11/23/1998	EDWARD L. CARVER	116310.014	1963

21832 7590 11/17/2003

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/17/2003

39

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/198,004

Applicant(s)

CARVER ET AL

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,31 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,31 and 33-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-6,31 and 33-47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by EP 0107333.

See the appropriate paragraph of paper 25.

Additionally, Applicants' have characterized EP 0107333 as teaching a single reagent mixture added to a single sample. Applicants' state the instant invention teaches mixing a plurality of reagent mixtures with a sample prior to analysis.

With respect to the apparatus claims, these remarks are not convincing because the apparatus taught by EP 0107333 teaches a structure (e.g. multiple valves feeding into a single chamber for mixing) indistinguishable from that claimed.

The method claims are directed to "pumping each of a plurality of reagent mixture components including the sample of blood ...". The Office has read the claim as providing more than one stream, which includes the sample of blood. EP 0107333 meets this limitation by teaching the addition of a reagent mixture to the blood and the appropriate buffers, sheath fluids, etc.

Claims 1,3-6,31 and 33-47 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Carver et al. (USP 5,380,491).

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Carver et al. teach a method and apparatus for hematology analysis where lysing agents "A" and "B" are added to a sample and mixed in a curette prior to analysis (see columns 2-4 and figure 1).

Claims 1,3-6,31 and 33-47 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yamamoto et al.

Yamamoto et al. teach an automated blood analyzer that adds multiple reagents to a sample prior to analysis.

Applicant's arguments filed 8/27/03 have been fully considered but they are not persuasive.

Applicants' state EP '333, Carver et al. and Yamamoto et al. do not teach the claimed combination of means for combining at least one reagent mixture component stream into at least one other reagent mixture component stream for mixing a plurality of components into a combined stream.

Specifically, Applicants state even though EP '333 teaches three blood sample-reagent mixture and three sheath liquids, the concomitant flow is not mixed within the flow cell. These remarks are not commensurate in scope with the pending claims. The instant claim language of mixture is interpreted as a composition of different components, which clearly reads on the taught sheath fluid/blood/reagent mixture. Furthermore, the instant language does not specify anything about the status of the mixture in a flow cell or when the samples are mixed. Applicants' further state EP '333 only mixes when discarded as waste. EP '333 teaches in the last paragraph on page 4 through page 5 "... comitant supply of a first fluid from a selected one of a plurality of

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separate sources of different fluids, and a second fluid from a selected one of a plurality of separate sources of different second fluids... thereby enabling concomitant flow of said first and second fluids through said sheath stream flow cell ". This clearly teaches a mixture of first and second fluids simultaneously through the flow cell. The instant claim language of "mixture" does not distinguish over the mixture of first and second fluids in the flow cell as taught by EP '333.

Applicants' state Yamamoto et al. and Carver et al. both fail to teach the claimed mixture of at least two reagent streams into a single stream. Yamamoto et al. teach a sample (1) mix split at proportioning cock (2) and diluted at chambers (3,4). Chamber (7) adds hemolytic reagents, etc. Carver et al. is similar in teachings. The cumulative addition of reagent at each stage has been read on the claimed different reagent mixtures. Also, the method of intended use of the pending apparatus claims is of no patentable moment (e.g. Yamamoto et al. and Carver et al. have the capability/means to add multiple reagents to the sample stream and are indistinguishable from the instant claim language).

Applicants' conclude the above art fail to teach means for combining at least two reagent/mixture streams. The Office maintains the cited prior art all have the capability to perform the claimed function and the method of intended use of the apparatus is of no patentable moment with respect to the pending apparatus claims.

With respect to claim 42, Applicants' put forth the same arguments as above that EP '333 fails to teach mixing of at least two streams. The Office maintains EP '333 teaches concomitant flows where multiple streams are present and thus mixed and

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properly read on the instant claims. Similarly, Applicants refute the application of Yamamoto et al. and Carver et al. as above. The Office maintains these rejections are proper as the art teaches structurally indistinguishable devices.

With respect to claim 31 Applicants' state EP '333 fails to teach a method of mixing a plurality of different reagents into a single stream. The Office maintains the rejection is proper for the above reasons. The instant claim language does not distinguish the claimed mixture from the mixture taught by EP '333. The Office maintains Yamamoto et al. and Carver et al. teach a method of sequentially mixing more than one agent into a sample stream and have been properly applied to the instant claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9319.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
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